Remarks

Claims 18 and 20-27 were pending in the subject application. By this Amendment, the applicants have amended claim 18 and have canceled claim 27. No new matter has been added by these amendments. Support for the amendments can be found throughout the subject specification including, for example, at page 12, lines 12-23 and previously pending claim 27, which has now been incorporated into claim 18. Accordingly, claims 18 and 20-26 are currently before the Examiner for consideration. Favorable consideration is respectfully requested.

The amendments presented herein have been made to lend greater clarity to the claimed subject matter and to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants wish to thank Examiner Kwon for the courtesy extended to the undersigned during the personal telephonic interview conducted on March 3, 2010. This response and the amendments set forth herein are submitted in accordance with the substance of that interview. Specifically, the applicants have chosen to expedite prosecution of the current case by focusing the claims at this time on the applicants' unique and advantageous methods for treating stress-related symptoms following a stressful event selected from work stress, school stress, sports stress, divorce, bereavement, unemployment, moving from a house, and alcohol use.

Claims 18, 20-22 and 24-27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bernton *et al.* (U.S. Patent No. 5,605,885). The applicants respectfully traverse this rejection to the extent that it might be applied to the claims now presented for examination because the cited reference does not teach either the stressful events or the stress-related symptoms of the claimed method.

In order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v.*

> *Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

As amended, the applicants' claims require that cysteamine is administered to treat stress-related symptoms that result from a stressful event. The claims further require that the stress-related symptoms be selected from the following list: uncontrollable shaking; hyperventilation; vomiting; triggering of an asthma attack; periods of irritability or anger; apathy; depression; constant anxiety; irrational behavior; loss of appetite; comfort eating; lack of concentration; lack of sex-drive; increased smoking, drinking, or recreational drug-taking; excessive tiredness; skin problems; aches and pains resulting from tense muscles; increased pain from arthritis; heart palpitations; irregular menstruation cycles; constipation; diarrhea; dizziness; fainting spells; nail biting; frequent crying; sensation of pins and needles; increased tendency to perspire; and difficulty sleeping. In addition, cysteamine is administered prior to a stressful event that was previously listed in claim 27, now incorporated into claim 18. None of these elements are taught or suggested by the Bernton *et al.* reference.

Bernton *et al.* describe methods for stimulating a suppressed or deficient immune system by regulating the blood levels or activity of the hormone prolactin (see, for example, col. 4, lines 17-22). One method includes increasing prolactin levels endogenously via the administration of cysteamine (see, col. 5, lines 5-8). Nowhere do Bernton *et al.* describe the administration of cysteamine, prior to a stressful event, to treat stress-related symptoms, let alone those symptoms listed in the pending claims. Moreover, Bernton *et al.* also do not teach or suggest administering cysteamine prior to any of the following stressful events: work stress, school stress, sports stress, divorce, bereavement, unemployment, moving from a house, and alcohol use, in order to treat the symptoms listed above. Accordingly, the applicants respectfully submit that Bernton *et al.* teach methods with very different therapeutic utility for a different purpose (that being immunostimulation via prolactin receptor

upregulation as opposed to treatment of stress-related symptoms from stressful events as recited in the pending claims).

Therefore, Bernton *et al.* does not disclose or suggest the applicants' method, as currently claimed. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Bernton *et al.* reference.

Claim 23 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Bernton *et al.* in view of McCleary (U.S. Patent No. 6,964,969). The applicants respectfully traverse this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the claimed subject matter.

As noted above, there is no description or teaching by Bernton *et al.* regarding the ability of cysteamine to treat stress-related symptoms from a stressful event, particularly where cysteamine is administered prior to the stressful event. McCleary does not cure or even address the deficiencies identified in the Bernton *et al.* reference. Specifically, McCleary fails to teach or suggest administering cysteamine, or a salt thereof, to a patient to treat stress-related symptoms.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ (2007).

Morever, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined.

Because Bernton *et al.* and McCleary fail to teach or suggest combining cysteamine with another therapy for stress, or that this combination would produce an excellent therapeutic effect (treatment of stress-related symptoms in the patient following a stressful event), the subject invention cannot be said to be obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a)

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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